UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

WALGREEN CO., THE KROGER CO., SAFEWAY INC., HEB GROCERY COMPANY L.P. and ALBERTSON'S LLC, Plaintiffs, vs. BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, BOEHRINGER INGELHEIM INTERNATIONAL GMBH; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; TEVA PHARMACEUTICALS USA, INC.; BARR PHARMACEUTICALS INC.; BARR LABORATORIES, INC.; TEVA WOMEN'S HEALTH, INC. f/k/a DURAMED PHARMACEUTICALS INC.; AND DURAMED PHARMACEUTICALS SALES CORP. Defendants.	Civil Action No._____ JURY TRIAL DEMANDED

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Walgreen Co., The Kroger Co., Safeway Inc., HEB Grocery Company L.P. and Albertson's LLC bring this civil action against Defendants Boehringer Ingelheim Pharma GmbH & Co. KG ("BIPKG"), Boehringer Ingelheim International GmbH ("BI") and Boehringer Ingelheim Pharmaceuticals, Inc. ("BPI") (collectively, "Boehringer"); Teva Pharmaceuticals USA, Inc. ("Teva"); Barr Pharmaceuticals Inc. and Barr Laboratories, Inc. (collectively "Barr"); Teva Women's Health, Inc., formerly known as Duramed Pharmaceuticals Inc. ("DPI"); and Duramed Pharmaceuticals Sales Corp. ("DPSC") (collectively "Duramed") (collectively,

"Defendants"), under the antitrust laws of the United States. For their Complaint, Plaintiffs allege as follows:

I. INTRODUCTION

1. This is a civil antitrust action seeking treble damages and other relief arising out of Defendants' unlawful exclusion of generic competition from the market for the brand-name drug Aggrenox. Aggrenox is a capsule that combines 200 mg extended release dipyridamole and 25 mg acetylsalicylic acid, is indicated to reduce the risk of stroke in patients who have had transient ischemic attack (TIA) or stroke due to blood clot, and has been sold by Boehringer since 1999.

2. Barr received final approval from the FDA for its generic Aggrenox on August 14, 2009. Notwithstanding that it has had approval for its generic Aggrenox for over five years, Barr and its successor Teva have not launched generic Aggrenox because Barr entered into a reverse payment agreement and market allocation scheme with Boehringer in August 2008, which Teva later joined, pursuant to which Boehringer agreed to share its monopoly profits with Barr (through its subsidiary Duramed) in exchange for Barr's agreement to drop its challenge to Boehringer's '577 patent and to delay the launch of a generic Aggrenox until as late as July 2015.

3. In the absence of the illegal reverse payment transaction and market allocation scheme, Barr/Teva would have (i) reached a pro-competitive settlement with Boehringer that did not include illegal financial inducements and thus would have included an earlier licensed entry date prior to July 2015, and Barr/Teva would have launched at that time; (ii) launched generic Aggrenox after prevailing in the patent litigation; or (iii) launched generic Aggrenox at risk after the expiration of the 30 month stay, i.e., after November 30, 2009.

4. As a result of Defendants' unlawful conduct, competition in the market for 200 mg extended release dipyridamole and 25 mg acetylsalicylic acid capsules has been delayed until as late as July 2015, and Plaintiffs and/or their assignors have incurred significant overcharges on their purchases of branded Aggrenox.

5. Since Aggrenox's approval by the Food and Drug Administration ("FDA") in 1999, Boehringer has been able to charge monopoly prices and earn monopoly profits on Aggrenox.

6. Generic versions of brand-name drugs are less expensive than the brand-name drug. Once an AB rated generic becomes available, purchasers typically switch rapidly from a brand to a generic, with the result that the brand name manufacturer, in this case Boehringer, loses approximately 90% of its sales within 90 days of the launch of the generic.

7. On or about May 31, 2007, Barr notified Boehringer that it had filed an Abbreviated New Drug Application ("ANDA") seeking approval for a generic Aggrenox, with a Paragraph IV certification with respect to Boehringer's U.S. Patent No. 6,015,577 (the "'577 Patent") (which expires in January 2017). Subject to certain confidentiality restrictions, Barr also offered to provide Boehringer with access to its ANDA. Barr's ANDA and Paragraph IV threatened Boehringer's continued receipt of monopoly profits on Aggrenox.

8. In response to Barr's Paragraph IV certification, on July 11, 2007, Boehringer sued Barr for infringement of the '577 Patent, thereby triggering an automatic stay of the FDA's approval of Barr's generic ANDA for up to 30 months, i.e., until November 30, 2009. In response, Barr denied infringement and also filed counterclaims, seeking, among other things, a judicial determination that the '577 was invalid.

9. To avoid the loss of its Aggrenox monopoly profits and a judicial determination that its '577 patent was invalid, in August 2008, Barr and Boehringer entered into an unlawful reverse payment transaction. On August 11, 2008, Boehringer and Barr signed a Settlement Agreement and a License and Supply Agreement, and Boehringer and Barr's subsidiary, Duramed, signed a Co-Promotion Agreement. These three agreements are collectively referred to herein as "the reverse payment agreement." Pursuant to the reverse payment agreement, Boehringer agreed to share its Aggrenox monopoly profits with Barr (directly and through its subsidiary) in exchange for Barr dropping its challenge to the '577 patent and delaying the launch of its generic Aggrenox until as late as July 2015.

10. The Co-Promotion Agreement was the vehicle through which Boehringer agreed to provide Barr with large cash payments in exchange for Barr's agreeing to delay the launch of its generic Aggrenox product. Boehringer has admitted in pleadings filed in an FTC enforcement proceeding that (i) the Co-Promotion Agreement was an integral part of the settlement of the patent litigation and that forecasts Boehringer prepared analyzing the Co-Promotion Agreement were created in connection with analyzing the settlement of the patent litigation; and (ii) it would not have entered into the Co-Promotion Agreement absent settlement of the patent litigation. Additionally, the royalties that Boehringer agreed to pay Barr are based on net sales of Aggrenox, not the success of Barr's co-promotion efforts. Further, the targeted physicians under the Co-Promotion Agreement were obstetricians and gynecologist. Given the warnings in the Aggrenox label, these physicians are likely to have a limited number of patients for whom they would prescribe Aggrenox. The payments, which have been estimated by the Federal Trade Commission to be in excess of $120 million over seven years, are far in excess of the value of any co-promotion services performed by Barr/Duramed.

11. The approximately $120 million being paid to Barr, directly and/or through its subsidiary Duramed, constitutes a large and unexplained reverse payment within the meaning of *Federal Trade Comm'n v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), in that the amount paid significantly exceeds the sum of the litigation costs that Boehringer saved by settling the patent case and the value of the services rendered by Boehringer under the Co-Promotion Agreement.

12. In addition to guaranteeing Barr large cash payments in exchange for agreeing to delay the launch of generic Aggrenox, Boehringer also provided Barr significant economic value under the terms of the Supply Agreement as part of the consideration for Barr's agreeing to delay the launch of its generic Aggrenox. Based upon information and belief, pursuant to the Supply Agreement, Boehringer agreed that it would not compete with Barr by selling an authorized generic during Barr's 180 days of exclusivity. This agreement has an economic cost to Boehringer and an economic value to Barr that is worth many millions of dollars—again, far in excess of any saved litigation costs.

13. Barr was the first generic manufacturer to file an ANDA with a Paragraph IV certification with respect to the '577 Patent. Accordingly, under 21 U.S.C. § 355(j)(5)(B)(iv), Barr was eligible for 180 days of marketing exclusivity during which the FDA would not give final approval to any other ANDA filer's generic Aggrenox. The 180-day exclusivity was potentially very valuable to Barr because, during the 180 days of exclusivity, Barr would be able to charge prices that are higher than it could charge if other AB-rated generic products were in the market and also capture 100% of the generic sales.

14. However, the 180-day exclusivity period does not bar a brand manufacturer from selling an authorized generic or entering into a licensing agreement with another company to allow another company to sell an authorized generic under the brand company's NDA. If a

brand manufacturer sells an authorized generic (or allows another company to do so) during the 180-day exclusivity period, then the first ANDA filer's profits are significantly reduced. The authorized generic will force the price of both generics to be lower and will also result in the first ANDA filer losing sales to the authorized generic. Thus, Boehringer's agreement not to compete with Barr during Barr's 180 days of exclusivity will allow Barr to have 100% of the generic market and to sell generic Aggrenox at a higher price than the price it could charge if there were competition from an authorized generic. Boehringer has a history of launching authorized generics, reflecting Boehringer's belief that it is financially beneficial for them to do so.

15. Defendants' reverse-payment agreement was intended to and has in fact (i) precluded entry of a less expensive 200 mg extended release dipyridamole/25 mg acetylsalicylic acid capsules (*i.e.*, generic Aggrenox); (ii) fixed, raised, maintained or stabilized the prices of 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules; (iii) permitted Boehringer to monopolize the market for 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules in the United States; (iv) allocated 100% of the 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsule market in the United States to Boehringer; and (v) allocated 100% of the market for generic 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules in the United States to Barr for six months after Barr's eventual launch of its generic.

16. Absent Defendants' unlawful reverse payment agreement, Barr/Teva would have launched a generic Aggrenox years ago and Plaintiffs would have been able to purchase generic 200 mg extended release dipyridamole/25 mg acetylsalicylic acid capsules at significantly lower prices than they were forced to pay for branded Aggrenox.

17. Boehringer's monopoly power in the 200 mg extended release dipyridamole/25 mg acetylsalicylic acid capsules market was maintained through willfully exclusionary conduct, as distinguished from growth or development as a consequence of a legally obtained valid patent, other legally obtained market exclusivity, a superior product, business acumen or historical accident.

18. Plaintiffs are direct purchasers or assignees of direct purchasers of Aggrenox and are included in the proposed class definition in actions currently pending as part of *In re Aggrenox Antitrust Litigation*, MDL Docket No. 2516, in the MDL transferee court. The limitations period applicable to Plaintiffs' claims has been tolled since the filing of the first class action on behalf of direct purchasers of Aggrenox.

II. THE PARTIES

19. Plaintiff Walgreen Co. ("Walgreen") is an Illinois corporation having its principal place of business at 200 Wilmot Road, Deerfield, Illinois 60015. Walgreen owns and operates retail stores in several states at which it dispenses prescription drugs, including Aggrenox, to the public. Walgreen brings this action in its own behalf and as the assignee of Cardinal Health, Inc. ("Cardinal"), a pharmaceutical wholesaler, which during the relevant period purchased Aggrenox directly from Boehringer for resale to Walgreen and which has assigned its claims arising out of those purchases to Walgreen. In addition, Walgreen is contractually entitled to a second assignment from AmerisourceBergen Drug Corporation ("ABDC"), another pharmaceutical wholesaler, which during the relevant period purchased Aggrenox directly from Boehringer for resale to Walgreen. Walgreen intends to include purchases made through ABDC in its damage claim upon receipt of that second assignment.

20. Plaintiff The Kroger Co. ("Kroger") is an Ohio corporation having its principal place of business at 1014 Vine Street, Cincinnati, Ohio 45202. Kroger owns and operates retail

stores in several states at which it dispenses prescription drugs, including Aggrenox, to the public. Kroger brings this action in its own behalf and as the assignee of Cardinal, which during the relevant period purchased Aggrenox directly from Boehringer for resale to Kroger and which has assigned its claims arising out of those purchases to Kroger.

21. Plaintiff Safeway Inc. ("Safeway") is a Delaware corporation having its principal place of business at 5918 Stoneridge Mall Road, Pleasanton, California 94588. Safeway owns and operates retail stores in several states at which it dispenses prescription drugs, including Aggrenox, to the public. Safeway brings this action in its own behalf and as the assignee of Cardinal, which during the relevant period purchased Aggrenox directly from Boehringer for resale to Safeway and which has assigned its claim arising out of those purchases to Safeway.

22. Plaintiff HEB Grocery Company L.P. ("HEB") is a Texas limited partnership having its principal place of business at 646 South Main Avenue, San Antonio, Texas 78204. HEB owns and operates retail stores at which it dispenses prescription drugs, including Aggrenox, to the public. HEB brings this action in its own behalf and as the assignee of Cardinal and McKesson Corporation ("McKesson"), another pharmaceutical wholesaler, which during the relevant period purchased Aggrenox directly from Boehringer for resale to HEB and which have assigned their claims arising out of those purchases to HEB.

23. Plaintiff Albertson's LLC ("Albertson's") is a Delaware limited liability company having its principal place of business at 250 Parkcenter Boulevard, Boise, Idaho 83706. Albertson's owns and operates retail stores in several states at which it dispenses prescription drugs, including Aggrenox, to the public. Albertson's brings this action in its own behalf and as the assignee of McKesson, which during the relevant period purchased Aggrenox directly from

Boehringer for resale to Albertson's and which has assigned a portion of its claims arising out of those purchases to Albertson's.

24. Defendant Boehringer Ingelheim Pharma GmbH & Co. KG ("BPIKG") is limited partnership organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

25. Defendant Boehringer Ingelheim International GmbH ("BII") is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

26. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield Connecticut 06877.

27. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation having its principal place of business at 1090 Horsham Road, P. O. Box 1090, North Wales, Pennsylvania.

28. Prior to their acquisition by Teva in December 2008, Defendants Barr Pharmaceuticals Inc. and Barr Laboratories, Inc. were Delaware corporations having their principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. In December 2008, Barr Pharmaceuticals, Inc. was acquired by Teva and became a wholly-owned subsidiary of Teva. At the same time Barr Laboratories, Inc. merged into and became a division of Teva.

29. Defendant Duramed Pharmaceuticals Inc. is a Delaware corporation having its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Until 2008, Duramed was a subsidiary of Barr. In 2008, when Teva purchased Barr, Duramed became a subsidiary of Teva. Duramed is now known as Teva Women's Health, Inc.

30. Defendant Duramed Pharmaceutical Sales Corp. ("DSPC") is a Delaware corporation having its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Until 2008, DPSC was a subsidiary of Barr. In 2008, when Teva purchased Barr, DPSC became a subsidiary of Teva and is now known as Teva Sales and Marketing, Inc.

III. JURISDICTION AND VENUE

31. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, to recover threefold damages, permanent injunctive relief, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiffs resulting from Defendants' unlawful scheme excluding and delaying generic competition to Aggrenox, as hereinafter alleged. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

32. Defendants transact business within this district and/or have an agent and/or can be found in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, as well as 28 U.S.C. §1391(b) and (c).

IV. OPERATIVE FACTS

A. Characteristics of the Prescription Pharmaceutical Marketplace

33. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's choice of products and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

34. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Aggrenox, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

35. Boehringer and other brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

36. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand – the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power. The result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

37. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

38. When the FDA approves a brand manufacturer's NDA, the drug product is listed in an FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." The manufacturer may list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may subsequently list in the Orange Book within thirty days of issuance any such patents issued after the FDA approves the NDA. 21 U.S.C. §§ 355(b)(1) & (c)(2).

39. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

C. The Hatch-Waxman Amendments

40. The Hatch-Waxman Amendments (also simply "Hatch-Waxman"), enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to

sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating.

41. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

42. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

43. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984,

prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009 total prescription drug revenue had soared to $300 billion.

D. Paragraph IV Certifications

44. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand drug has expired (a "Paragraph II certification");

iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

45. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

46. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity. This means that the first approved generic is the only available generic (other than an authorized generic, as discussed below) for at least six months. This 180-day exclusivity period is extremely valuable to generic companies. While only one generic is on the market, the generic price, while lower than the branded price, is much higher than after multiple generic competitors enter the market. Generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market. Being able to sell at the higher duopoly price for six months may be worth hundreds of millions of dollars.

47. The first generic applicant can help the brand manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic manufacturers. The first generic applicant, by agreeing not to begin marketing its generic drug, thereby delays the start of the 180-day period of generic market exclusivity, a tactic called exclusivity "parking." This tactic creates a "bottleneck" because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

48. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") in order to make it more difficult for brand and generic manufacturers to conspire in order to delay the start of the first-filer's 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an

ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their generic products.

49. Under the "failure to market" provision, a first ANDA applicant forfeits 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that qualified the first applicant for exclusivity (i.e., as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment that includes a finding that the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the Orange Book.

50. Brand manufacturers and first-filing generics can structure their settlements in order to intentionally skirt these forfeiture provisions. For example, manufacturers subvert the failure-to-market provision and keep the 180-day exclusivity bottleneck in place by, for example, settling their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a Paragraph IV certification, or seeking a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed. When that happens, in order to trigger forfeiture and gain access to the market, subsequent ANDA applicants are forced to obtain a judgment that all patents for which the first filing generic company filed Paragraph IV certifications are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action concerning patents that the brand manufacturer did not assert against it in Paragraph IV litigation.

E. The Benefits of Generic Drugs

51. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price: generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that, by one year after market entry, the generic version will take over 90% of the brand's unit sales and sell for 15% of the price of the brand name product. For retail pharmacy chains like Plaintiffs, an AB-rated generic typically achieves a 90% substitution rate in 90 days. As a result, competition from generic drugs is viewed by brand name drug companies like Boehringer as a grave threat to their bottom lines.

52. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally and substantially substitute for the generic version when presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by writing "dispense as written" or similar language on the prescription).

53. There is an incentive to choose the less expensive generic equivalent in every link in the prescription drug chain. Pharmaceutical wholesalers and retail pharmacies pay less to acquire generic drugs than to acquire the corresponding brand-name drug. Health insurers and patients also benefit from the lower prices that result from generic competition.

54. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supra-competitive prices. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market, including by using tactics such as the pay for delay agreement at issue here.

F. The Impact of Authorized Generics

55. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day period pursuant to its own approved NDA. Such an "authorized generic" is chemically identical to the brand drug, but is sold as a generic product by the brand manufacturer or through a third party. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the price of both generic drugs and, in addition, forces the first-filer to share the generic sales made at those lower prices with the brand-name manufacturer. Both of these effects reduce the first-filer's revenues and profits.

56. In its study, Authorized Generic Drugs: Short-term Effects and Long-Term Impact (August 2011) (the "FTC Study"), the Federal Trade Commission found that authorized generics capture a significant portion of sales, reducing the first-filer generic's revenues by approximately 50% on average during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the authorized generic takes a large share of unit sales away from the first filer; and (2) the presence of an additional generic in the market causes prices to decrease.

57. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, drug purchasers such as

Plaintiffs benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

58. As a practical matter, authorized generics are the only means by which brand-name manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand-name manufacturers generally do not reduce the price of their branded drug in response to the entry of an AB-rated generic. Instead, they either raise the price to extract higher prices from the small number of "brand-loyal" patients or, more typically, they continue to raise the price of the branded drug at the same intervals and at the same rate at which they raised the price of the drug prior to generic entry.

59. Given the significant negative impact of an authorized generic on the first-filing generic's revenues, and the absence of any other form of price competition from the branded manufacturer, a brand manufacturer's agreement not to launch an authorized generic has tremendous economic value to the generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such non-competition agreements deprive drug purchasers such as Plaintiffs of the lower prices resulting from two forms of competition: (1) among the branded and the generic products; and (2) between the generic products.

V. DEFENDANTS' ANTICOMPETITIVE SCHEME

A. Barr's ANDA for Generic Aggrenox and Boehringer's Suit for Patent Infringement

60. Boehringer is the holder of NDA No. 20-884, which the FDA approved in 1999 for 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules. The 200 mg dipyridamole/25 mg acetylsalicylic acid capsules described in Boehringer's NDA are prescribed to reduce the risk of stroke in patients who have had transient ischemia of the brain or completed

ischemic stroke due to thrombosis (*i.e.*, patients who have previously suffered a stroke). The Aggrenox label indicates that it should not be used in the third trimester of pregnancy and that there are risks to the fetus associated with the use of Aggrenox by pregnant women. Additionally, the patient information sheet states that before using Aggrenox, the patient should tell the doctor if she is pregnant or plans to become pregnant, or if she is breast-feeding or plans to do so, because of the risks to the fetus and baby.

61. Either directly or through affiliates BII and BIPI, Boehringer owns the '577 patent, which issued on January 18, 2000. After receiving FDA approval, Boehringer listed the '577 patent in the "Orange Book" as a patent relating to Aggrenox.

62. In January 2007, Barr submitted ANDA No. 78-804 to the FDA, seeking approval to market a generic equivalent of 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules. On or about May 31, 2007, Barr notified Boehringer that it had filed ANDA No. 78-804. Barr's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic Aggrenox product would not infringe any valid claim of the '577 patent and challenging the validity of the '577 patent. In that letter, Barr also made an offer to provide its ANDA to Boehringer with certain confidentiality provisions.

63. As the first filer of an ANDA with a Paragraph IV certification for generic Aggrenox, Barr was potentially entitled to 180 days of marketing exclusivity, i.e., 180 days free from competition with other ANDA generic Aggrenox products. However, as noted above, this exclusivity did not protect Barr from competition from a less expensive authorized generic version of Aggrenox.

64. On July 11, 2007, Boehringer sued Barr in the United States District Court for the District of Delaware (docketed as 07-cv-00432), alleging that Barr's filing of its ANDA infringed

the ‘577 patent. Boehringer’s infringement suit triggered a 30-month stay prohibiting the FDA from granting Barr final approval to launch a generic equivalent of Aggrenox until the earlier of: (1) a final judgment that the ‘577 patent was invalid or not infringed; or (2) November 30, 2009. Barr filed an answer and a counterclaim, seeking declaratory judgments that: (1) the ‘577 patent was invalid; (2) Barr’s proposed generic product did not infringe the ‘577 patent; and (3) the ‘577 patent was unenforceable for inequitable conduct.

65. If Barr were successful in defeating Boehringer’s patent infringement claim, not only would Barr be able to start competing with its lower-priced generic Aggrenox product, but such a result would also lead to competition from other generic manufacturers (including at least an authorized generic). Both Barr and Boehringer knew that when a generic version of a brand-name drug enters the market, the brand manufacturer loses most of its sales within a short period of time as purchasers switch from buying the brand to buying the less expensive generic.

B. Barr’s and Boehringer’s Illegal Scheme to Allocate the Market

66. To avoid the loss of Boehringer’s Aggrenox patent and Aggrenox monopoly profits, Boehringer and Barr engineered a scheme, which Teva later joined, whereby Boehringer (i) paid Barr, through its subsidiary, large and unjustified amounts of money over a seven-year period, with the prospect of additional profits thereafter, as compensation and consideration for Barr dropping its challenge to Boehringer’s ‘577 patent and refraining from selling a lower-priced generic version of Aggrenox until as late as July 1, 2015; and (ii) agreed it would not compete with Barr by means of an authorized generic during Barr’s first six months selling generic Aggrenox.

67. On August 11, 2008, prior to the parties’ submitting claims construction briefs, and while the litigation was in its early stages, Boehringer and Barr settled the ‘577 patent

litigation by entering into a reverse payment settlement agreement. Based on information and belief, Barr agreed to drop its challenges to the '577 patent and to refrain from launching a generic equivalent of Aggrenox until as late as July 1, 2015 in exchange for Boehringer's agreeing to share its monopoly profits with Barr by: (a) agreeing not to compete with Barr with an authorized generic during Barr's 180-day exclusivity; and (b) agreeing to pay Barr, through its subsidiary Duramed, at least $120 million over seven years pursuant to a pretextual co-promotion agreement. These commitments were contained in two related written contracts signed on the same day. The combined effect of these agreements was to transfer millions of dollars of Boehringer's monopoly profits on Aggrenox to Barr.

68. The payments Boehringer agreed to make to Barr (through its subsidiary) pursuant to the terms of the Co-promotion Agreement were large and unjustified. Based upon information and belief, pursuant to the terms of the co-promotion agreement, Boehringer agreed to pay Barr a one-time fee plus annual, increasing royalties on total U.S. Aggrenox sales, purportedly for promoting Aggrenox to doctors whose specialize in gynecology and obstetrics, such payments estimated to amount to over $100 million over a seven year period. Based on information in the Aggrenox label, however, Aggrenox is risky for women who are or may become pregnant and is explicitly not for use in patients that are in the third trimester of pregnancy.

69. Boehringer's payments under the terms of the Co-Promotion Agreement were far in excess of any saved litigation costs plus the value of the services that Barr's subsidiary, Duramed, performed. While the Co-Promotion Agreement is not publicly available, Boehringer has admitted in proceedings relating to the Federal Trade Commissions' ("FTC") enforcement of an FTC subpoena that the Co-Promotion Agreement was "inextricably

intertwined" with the agreement to settle the patent litigation. Boehringer also argued that its financial analysis of the Co-Promotion Agreement created prior to the settlement is protected from discovery because it was part of its analysis of the settlement agreement. Thus, Boehringer has admitted that the significant and large payments it agreed to make pursuant to the Co-Promotion Agreement were part of the consideration for the settlement of the patent litigation, *i.e.,* Barr's agreeing to delay the launch of generic Aggrenox until as late as July 2015.

70. Additionally, in his opinion on the FTC's enforcement action, the presiding Magistrate Judge found that the Co-Promotion Agreement was integral to the settlement of the patent litigation. Specifically, Magistrate Judge John M. Facciola stated:

> BIPI [Boehringer] claims that, while the co-promotion agreement was "freestanding," in that it constituted a separate business arrangement, the terms of the co-promotion agreement were indeed part of the litigation settlement and the two processes informed one another. BIPI asserts that the co-promotion agreement arose during the settlement discussions and, in fact, was part of the settlement.
>
> After reviewing these documents, the status reports and oppositions, and affidavits accompanying the in camera submissions, I agree that the co-promotion agreement was an integral part of the litigation.

See Memorandum Opinion dated 09/27/2012, D.D.C., Case No. 09-mc-00564 (Doc. No. 69), at p. 10.

71. The approximately $120 million being paid over time to Barr/Duramed constitutes a large and unexplained reverse payment, within the meaning of *Federal Trade Comm'n v. Actavis, Inc*., 133 S. Ct. 2223 (2013), in that it significantly exceeds the sum of the litigation costs saved by Boehringer in settling the patent litigation and the value of any services received by Boehringer in exchange for the payment.

72. Likewise, although the terms of the Supply and License Agreement are not public, based upon information and belief, under the terms of the Supply and License Agreement, Boehringer agreed that it would not compete against Barr with an authorized generic during Barr's 180-day exclusivity period in return for Barr's agreement to delay the launch of a generic version of Aggrenox until as late as July 2015. As experienced companies in the pharmaceutical business, both Barr and Boehringer knew such an agreement was extremely valuable to Barr. If a branded company chooses to launch an authorized generic, it will greatly diminish the profit potential of the first ANDA filer's product both by taking away sales from the ANDA filer and by substantially reducing generic prices. An authorized generic also diminishes the first filer's long-term first-mover advantage. As experienced pharmaceutical companies, Barr and Boehringer understood these market dynamics.

73. Boehringer has launched at least six authorized generics between 1999 and 2014. In at least four of those instances, Boehringer launched an authorized generic through its subsidiary Roxane Laboratories, Inc. Upon information and belief, Boehringer would have launched an authorized generic version of Aggrenox upon market entry by Barr/Teva in the absence of the Reverse Payment Agreement here. Boehringer's agreement to forgo launching an authorized generic was to its financial detriment and it would have been economically irrational for Boehringer to have so agreed in the absence of Barr's agreement to delay the launch of its generic Aggrenox product.

74. The reverse payment agreement between Boehringer and Barr also created a scenario in which Barr could serve as the "cork in the bottle" that would prevent any generic filer from launching prior to July 2015 so long as Barr maintained its first-to-file status and Boehringer prevented any subsequent generic filer from invalidating the '577 patent. To date, at

least three other generic manufacturers have filed ANDAs for generic Aggrenox. However, there is no generic Aggrenox currently sold in the United States.

75. Instead of competing, which would have resulted in lower prices, Barr and Boehringer agreed, under the terms of the reverse payment agreement, to keep prices at supra-competitive levels. Barr agreed to delay marketing generic Aggrenox until July 2015, during which Boehringer has continued to reap monopoly profits from the sale of Aggrenox, which are then shared with Barr, through Barr's subsidiary, under the Co-Promotion Agreement.

C. Boehringer Admits During the FTC Proceedings That the Co-Promotion Agreement was Consideration for the Settlement

76. Under the MMA, the settlement and commercial agreements were required to be filed with the FTC. On January 15, 2009, the FTC opened a formal investigation into the Boehringer-Barr settlement. As a part of that investigation, on February 5, 2009, the FTC issued a subpoena *duces tecum* to Boehringer requiring Boehringer to produce documents and data relating to litigation regarding Aggrenox; documents regarding sales, profits, and marketing plans for Aggrenox; documents relating to the agreements between Boehringer and Barr entered at the time of the settlement of the patent litigations; documents relating to Boehringer's co-marketing of products (including Aggrenox) with other firms; documents relating the marketing of authorized generic versions of Boehringer's products; and analyst reports relating to Aggrenox. According to pleadings filed by the FTC, Boehringer did not respond to the subpoena in good faith and in October 2009, the FTC filed an action to enforce the subpoena.

77. The record in the FTC subpoena enforcement action against Boehringer reveals Boehringer's admission that the Co-Promotion Agreement was part of the consideration for the settlement of the patent infringement lawsuit and that Boehringer would not have agreed to enter the Co-Promotion Agreement absent Barr agreeing to settle the patent lawsuit and delay the

launch of generic Aggrenox. For example, during a December 9, 2011, hearing in connection with the FTC's motion to compel, Boehringer's lawyer stated:

> We have always said that the Aggrenox co-promote was part of the settlement.
>
> It had – It absolutely was. It's plain from the face of the documents.

See Transcript of 12/09/2011 Status Hearing Before the Honorable John M. Facciola, United States Magistrate Judge, D.D.C., Case No. 09-mc-00564, at 36:19-21.

78. In 2012, the FTC appealed the district court's ruling denying its petition to the Federal Circuit. In its August 28, 2013 Appellee Brief, Boehringer stated that "it is not difficult to understand why parties engaged in contentious litigation would not otherwise be willing to do business with each other." *See* Brief of Respondent-Appellee Boehringer Ingelheim Pharmaceuticals, Inc., U.S.C.A., D.C. Circuit, No. 12-5393, at p. 42. This statement is another indication that the Co-Promotion Agreement with its multi-million dollar payments, which was signed the same day as the Settlement Agreement, was a necessary part of the patent settlement. Indeed, the Co-Promotion Agreement was explicitly contingent on execution of the Settlement Agreement, and would have "no force or effect" until the patent litigation was dismissed.

79. Prior to Boehringer's statements in the FTC proceedings, neither Barr, Teva, nor Boehringer disclosed that the Co-Promotion agreement was part of the consideration paid to Barr to settle the Aggrenox patent litigation and secure Barr's agreement to remain off the market. Additionally, the terms of the agreements have never been made public and Boehringer's conduct in responding to the FTC's subpoena reveals Boehringer's efforts to keep its economic analysis of the settlement hidden from scrutiny.

D. Pursuant to the Co-Promotion Agreement, Barr Receives Payments Well in Excess of the Value of the Services it Provides and Boehringer's saved litigation costs

80. Based upon information and belief, the Co-Promotion Agreement provided for payments in excess of $100 million to Barr, through its subsidiary, over a seven-year period purportedly for services related to the promotion of Aggrenox to gynecologist and obstetricians. The Aggrenox label states that women who are in the third trimester of pregnancy should not take Aggrenox and that women who are pregnant or may become pregnant should tell their doctor before taking Aggrenox. Thus, it is unlikely that co-promotion efforts to these physicians would be likely to generate a sufficient number of prescriptions to justify the payments. Indeed, the payments under the Co-Promote are tied to net sales, not to the success of the co-promotion efforts.

81. Further, while Boehringer has tried to justify the payments under the Co-Promotion Agreement based on the training and introduction of BIPI's sales force to potential customers of flibanserin, a drug under development by Boehringer to treat women with low libido, this argument is a pretext as well. At the time of the Co-Promotion Agreement, flibanserin had not been approved by the FDA, there was no guarantee it would be approved and, based upon information and belief, the payments that Boehringer agreed to make to Barr are not tied to the potential approval of flibanserin. In fact, when this product was rejected a second time by the FDA in 2010, Boehringer sold the product to another company, but upon information and belief, continued to make payments to Barr/Teva under the Co-Promotion Agreement.

82. Not only are the payments under the Co-Promotion Agreement far in excess of the value of the services that were to be rendered under the Co-Promotion Agreement, but the payments are far in excess of Boehringer's saved litigation costs. There was only a single patent

at issue. The court told the parties that (i) motions for summary judgment would not be entertained; (ii) the case would be tried in 5 days; and (iii) the case was set for trial in May 2009 and would be tried to the bench. Likewise, the economic value provided to Barr by Boehringer's promise not to launch an authorized generic were also far in excess of any saved litigation costs.

E. Boehringer and Barr Could Have Settled the Patent Litigation Without Any Payments

83. Defendants did not need to resort to payments from Boehringer to Barr in order to resolve their patent litigation. To the contrary, in 2004 and 2005, 27 out of 30 agreements between brand and generic manufacturers settling patent disputes contained no anticompetitive payment from the brand to the generic manufacturer. *See* FTC, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition (2006), available at http://www.ftc.gov/os/2006/04/fy2005drug settlementsrpt.pdf; FTC, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004: A Report by the Bureau of Competition (2005), available at http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf. Many of those 27 agreements allowed for entry of a generic drug before patent expiration. Those agreements took various forms, but many agreements resulted in either: (a) split patent life whereby the generic would enter the market before the expiry of the challenged patent but would not receive any payment; or (b) unrestricted generic entry immediately upon or very soon after the settlement, sometimes accompanied by a royalty payment from the generic manufacturer to the brand manufacturer. Id. In a more recent FTC analysis of settlement agreements filed with the FDA between January 1, 2004 and September 30, 2009 pursuant to the Medicare Prescription Drug, Improvement, and

Modernization Act of 2003, 152 out of 218 (or 70%) involved no compensation from the brand to the generic. *See* FTC, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions: A Federal Trade Commission Staff Study (January 2010), available at http://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff. The FTC analysis further reflects that with respect to the 66 settlement agreements that involved some form of compensation from the brand to the generic combined with a delay in generic entry, on average these agreements prohibit generic entry for nearly 17 months longer than agreements without payments. *Id.*

F. In the Absence of the Reverse-Payment Settlement, Teva/Barr Would Have Launched Prior to July 2015

84. In the absence of a settlement, Teva/Barr would have launched a generic Aggrenox well before July 2015 either by launching at risk following FDA approval after the expiration of the 30-month stay; by prevailing in the patent litigation; or by entering pursuant to a license granted as part of a settlement that did not include a large and unjustified payment. It is well known in the pharmaceutical industry that Teva has a history of launching generic versions of brand-name drugs at risk. Additionally, Teva possesses the financial wherewithal to cover any non-insured losses stemming from an at-risk launch.

G. Boehringer and Barr/Teva Have Acted in Accordance with the Agreements

85. On August 14, 2008, the Delaware District Court dismissed the Aggrenox patent infringement litigation. The Delaware District Court played no role other than signing the proposed Joint Stipulated Order of Dismissal. The Delaware District Court did not draft the language contained in the proposed order, and it made no changes to the proposed order before signing it on August 14, 2008. Nor did the court hold any hearings or conferences in connection with the dismissal. The Court simply adopted the proposed Stipulated Order of Dismissal.

86. On December 23, 2008, Barr became a wholly-owned subsidiary of Teva. Teva succeeded to Barr's liability and, in addition, has continued to perform under the terms of the reverse payment agreement. Teva thereby joined the unlawful agreement, collusion and conspiracy with respect to the suppression of generic competition for Aggrenox.

87. On August 14, 2009, Barr, now owned by Teva, received final FDA approval of ANDA No. 78-804, in part because the 30-month stay expired early upon dismissal of the patent litigation. Had the patent litigation not been dismissed, the 30-month stay would have expired on November 30, 2009. Pursuant to its predecessor's agreement with Boehringer, Teva has refrained from entering the market with a generic equivalent of Aggrenox, and Boehringer has continued to make payments to Teva.

88. Between August 2008 and the present, Boehringer has substantially raised the price for Aggrenox.

89. But for the Defendants' ongoing performance under the reverse payment agreement, generic competition for Aggrenox would have occurred by this time and Plaintiffs would have purchased less expensive generic Aggrenox in place of more expensive branded Aggrenox for the vast majority of their branded Aggrenox purchases. As of today, there is still no generic equivalent of Aggrenox on the market in the United States.

VI. ANTICOMPETITIVE EFFECTS OF DEFENDANTS' SCHEME

90. The reverse payment settlement discussed above has enabled the Defendants to: (a) prevent and delay the entry of less expensive generic versions of 200 mg extended release dipyridamole and 25 mg acetylsalicylic acid capsules in the United States; (b) fix, raise, maintain, or stabilize the price of 200 mg extended release dipyridamole and 25 mg acetylsalicylic acid capsules; (c) allocate 100% of the 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsule market in the United States to Boehringer; and (d) allocate 100%

of the generic 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsule market in the United States to Barr/Teva for six months after Barr/Teva's eventual launch.

91. Barr's ANDA was approved by FDA on August 14, 2009. But for the continuing illegal agreements between Barr and Boehringer, Teva would have begun selling a less expensive AB-rated generic version of Aggrenox some time after November 30, 2009, upon expiration of the 30-month stay. Such sales would have occurred via: (a) an agreement between Boehringer and Barr that did not include illegal reverse payments to delay generic entry and thus would have allowed for earlier market entry; (b) a launch "at risk" by Teva following expiration of the 30-month stay; or (c) a launch by Teva after prevailing in the patent litigation. In addition, upon market entry by Barr, Boehringer would have begun selling its own less expensive authorized generic version of Aggrenox in direct competition with the Barr generic.

92. Defendants' unlawful concerted action has delayed or prevented the sale of generic 200 mg extended release dipyridamole and 25 mg acetylsalicylic acid capsules in the United States and has unlawfully enabled Boehringer to sell Aggrenox at artificially inflated, supracompetitive prices without losing significant sales. But for Defendants' illegal, ongoing conduct, generic competition to Aggrenox would have occurred already because Teva would have launched its FDA-approved generic product and Boehringer would have launched an authorized generic product contemporaneously with that launch.

VII. INTERSTATE COMMERCE

93. The drugs at issue in this case are sold in interstate commerce. Defendants' unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce.

VIII. MARKET POWER AND MARKET DEFINITION

94. At all relevant times, Boehringer had market power over 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules because it had the power to maintain the price of the drug it sold as Aggrenox at supracompetitive levels without losing substantial sales to other products.

95. A small, but significant, non-transitory price increase for Aggrenox by Boehringer would not have caused a significant loss of sales to other stroke medications sufficient to make such a price increase unprofitable.

96. Aggrenox does not exhibit significant, positive cross-elasticity of demand with respect to price with any product (other than AB-rated generic versions of Aggrenox).

97. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which extended-release 200 mg dipyridamole/25 mg acetylsalicylic acid capsules are prescribed. Aggrenox has attributes significantly differentiating it from other stroke medications and making it unique. Aggrenox is the only anti-platelet drug that is specifically indicated to reduce the risk of stroke in patients who have had transient ischemia of the brain (mini stroke) or completed ischemic stroke due to thrombosis.

98. The existence of stroke medications other than Aggrenox did not constrain Boehringer's ability to raise or maintain prices without losing substantial sales, and therefore those other drug products are not in the same relevant antitrust product market with Aggrenox. Therapeutic alternatives are not necessarily economic substitutes.

99. To be a substitute for antitrust purposes, a functionally similar product must exert sufficient pressure on prices and sales of another product, so that the price of that product cannot be maintained above levels that would be maintained in a competitive market. No stroke medication other than AB-rated generic versions of Aggrenox will take away sufficient sales for

Aggrenox to prevent Boehringer from raising or maintaining the price of Aggrenox above levels that would prevail in a competitive market.

100. As noted above, price does not drive prescriptions for stroke medications (or other medications). Studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products.

101. Thus, unlike many consumer products where consumers are provided with a choice of functionally similar products at the point of sale and make purchasing decisions primarily based on price, the initial purchasing decision for prescription drugs, such as stroke medications, are made by the physician, not by consumers of those products.

102. The entry of other brand stroke medications (or generic versions of those other brands) did not take substantial sales from Aggrenox or cause Boehringer to lower its price. By contrast, the competitive impact of an AB-rated generic version of Aggrenox on brand Aggrenox would be substantial. Among other things, the entry of an AB-rated generic Aggrenox product would deliver hundreds of millions of dollars of savings to consumers.

103. Boehringer also sold Aggrenox at prices well in excess of marginal costs, and substantially in excess of the competitive price, and enjoyed high profit margins.

104. Defendants have had, and exercised, the power to exclude and restrict competition to Aggrenox and AB-rated bioequivalents.

105. Without the power to exclude and restrict competition to 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules (Aggrenox and AB-rated bioequivalent generics), and the concomitant ability to sell Aggrenox at prices well in excess of marginal costs, it would not have been economically rational for Boehringer to provide Barr with the large

financial inducements for the purpose of delaying Barr's launch of its AB-rated generic Aggrenox product. A firm that already has substantial competition has no economic incentive to pay an additional competitor large sums of money not to compete.

106. Boehringer, at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

107. To the extent that Plaintiffs are legally required to prove market power through circumstantial evidence by first defining a relevant product market, Plaintiffs allege that the relevant market is 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules (i.e., Aggrenox and its AB-rated generic equivalents). During the relevant time, Boehringer has been able to profitably maintain the price of 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules well above competitive levels.

108. The relevant geographic market is the United States and its territories.

109. At all relevant times, Boehringer's market share in the relevant market has been and remains 100%. Therefore, at all relevant times, Boehringer had monopoly power.

IX. EFFECT ON COMPETITION AND INJURY TO PLAINTIFFS

110. Defendants' unlawful exclusionary conduct has delayed or prevented the sale of generic 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules in the United States, and has unlawfully enabled Boehringer to sell 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules at artificially inflated, supracompetitive prices without losing significant sales. But for Defendants' illegal conduct, generic competition to Aggrenox would have occurred prior to July 2015 because (1) Barr/Teva would have entered with its generic version of Aggrenox after November 30, 2009 and before conclusion of the patent litigation; (2) Barr would have prevailed in the patent litigation; or (3) Boehringer and Barr would have agreed

to settle the patent litigation on terms that did not include exclusion payments and provided for generic entry earlier than July 2015.

111. If Teva/Barr had launched their generic version of Aggrenox, Plaintiffs and other purchasers would have substituted lower-priced generic 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules for the higher-priced brand name Aggrenox for the vast majority of their 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsule requirements.

112. During the relevant period, Plaintiffs and/or their assignors purchased substantial amounts of Aggrenox directly from Boehringer. As a result of Defendants' illegal conduct, Plaintiffs and other purchasers were compelled to pay, and did pay, artificially inflated prices for their 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsule requirements. Plaintiffs and other purchasers paid prices for 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules that were substantially higher than the prices that they would have paid but for the illegal conduct alleged herein. As a consequence, Plaintiffs and/or their assignors have sustained substantial injury to their business and property in the form of overcharges.

113. Defendants' anticompetitive scheme threatens continuing loss and injury to Plaintiffs unless enjoined by this Court.

114. Plaintiffs' injuries are injuries of the type the antitrust laws were designed to prevent and flow from that which makes Defendants' acts unlawful.

CLAIMS FOR RELIEF

Claim I: Violation of 15 U.S.C. § 2
Monopolization (Overall Scheme)
(Asserted Against Boehringer)

115. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 114 above as though fully set forth herein.

116. At all relevant times, Boehringer possessed substantial market power (i.e., monopoly power) in the relevant market. Boehringer possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

117. Through its overarching anticompetitive scheme, as alleged above, Boehringer willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and thereby injured Plaintiffs. Such conduct includes entering into the unlawful reverse payment agreement with Barr and continuing to adhere to that agreement thereafter. Boehringer's conduct was designed to delay the introduction of generic formulations of Aggrenox into the market.

118. It was Boehringer's conscious object to further its dominance in the relevant market by and through the overarching anticompetitive scheme.

119. Boehringer's scheme harmed competition.

120. There is and was no cognizable, non-pretextual pro-competitive justification for Boehringer's actions that outweighs the scheme's harmful effects. Even if there were some conceivable justification that Boehringer were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

121. As a direct and proximate result of Boehringer's illegal and monopolistic conduct, as alleged herein, Plaintiffs and/or their assignors have suffered injury to their business and property in an amount to be proven at trial.

Claim II: Violation of 15 U.S.C. § 2
Attempt to Monopolize
(Asserted Against Boehringer)

122. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 114 above as though fully set forth herein.

123. Boehringer, through its anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Boehringer's conscious objective to control prices and/or to exclude competition in the relevant market.

124. The natural and probable consequence of Boehringer's anticompetitive scheme, which was intended by, and plainly foreseeable to, Boehringer, was to control prices and exclude competition in the relevant market, to the extent that it did not succeed.

125. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Boehringer would succeed in and achieve its goal of maintaining monopoly power in the relevant market.

126. As a direct and proximate result of Boehringer's illegal and monopolistic conduct, Plaintiffs and/or their assignors have suffered injury to their business and property in an amount to be proven at trial.

Claim III: Violation of 15 U.S.C. § 1
Conspiracy in Restraint of Trade
(Asserted Against All Defendants)

127. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 114 above as though fully set forth herein.

128. Boehringer and Barr/Teva, their agents and affiliates and co-conspirators, both known and unknown, entered into and engaged in a continuing unlawful conspiracy in restraint of trade and commerce.

129. Beginning in or about August 2008, Boehringer and Barr (and Barr's successor Teva) commenced a continuing illegal contract, combination and conspiracy in restraint of trade, whereby Boehringer agreed to make large and unjustified payments to Barr/Teva in exchange for Barr's (and later Teva's) agreement to delay the launch of generic Aggrenox.

130. The purpose and effect of Defendants' reverse-payment agreement was to: (a) allocate all sales of 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules in the United states to Boehringer; (b) delay the sale of a generic version of 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules in the United States until as late as July 2015, and thereafter restrict the supply of generic versions of Aggrenox; (c) allocate all sales of generic 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid to Barr/Teva for six months after its belated launch of generic Aggrenox; and (d) fix the price which Plaintiffs and/or their assignors would pay for 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules at the higher, branded price. Absent the payments and other consideration provided to Barr pursuant to the reverse payment agreement, Barr would not have agreed to delay marketing a generic version of Aggrenox until as late as July 2015.

131. Defendants' unlawful reverse-payment conspiracy has had substantially adverse effects on competition in the relevant market and is unlawful under the rule of reason.

132. In the alternative, Defendants' conspiracy is a horizontal market-allocation agreement that allocates the market temporally rather than geographically and is unlawful *per se*. Pursuant to their agreement, Barr/Teva agreed not to compete with Boehringer from August 2008 until as late as July 2015, and Boehringer agreed not to compete with Barr/Teva for six months thereafter. Moreover, Boehringer's agreement not to launch an authorized generic in competition with Barr/Teva is an agreement to sell Aggrenox only at the higher branded price and not at the

lower generic price. Such an agreement between actual or potential competitors constitutes horizontal price-fixing and is unlawful *per se*.

133. Starting some time after November 30, 2009, and continuing to the present day, Plaintiffs and/or their assignors have been overcharged on their purchases of 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules.

134. But for Defendants' unlawful conspiracy, Barr would have begun selling a less expensive AB-rated generic version of Aggrenox some time after November 30, 2009 (upon the conclusion of the 30 month stay). Such sales would have occurred via (a) an agreement between Boehringer and Barr which did not include illegal reverse payments to delay generic entry and thus would have allowed for earlier market entry; (b) a launch "at risk" by Teva following termination of the 30 month stay; or (c) a launch by Teva after obtaining a favorable judgment in the patent litigation. Upon entry, Boehringer would have begun selling its own less expensive authorized generic version of Aggrenox.

135. Upon entry of generic versions of Aggrenox, Plaintiffs and/or their assignors would have substituted lower-priced generic 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules for the higher-priced brand-name Aggrenox for the vast majority of their 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsule requirements.

136. Plaintiffs and/or their assignors have purchased substantial amounts of Aggrenox directly from Boehringer. As a result of Defendants' illegal conduct, alleged herein, Plaintiffs and/or their assignors have been compelled to pay, and have paid, artificially inflated prices for their 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules requirements.

137. There is, and was, no legitimate, non-pretextual pro-competitive justification for Defendants' actions comprising the anticompetitive scheme that outweighs their harmful effect.

Even if there were some conceivable such justification, the scheme is and was broader than necessary to achieve such a purpose.

138. At all relevant times, Boehringer possessed market power in the relevant market. Boehringer possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

139. The goal, purpose and/or effect of the reverse payment agreement was to delay generic competition to Aggrenox and enable Boehringer to maintain its market power, *i.e.*, to continue charging supracompetitive prices for Aggrenox without a substantial loss of sales. Pursuant to the terms of the reverse payment agreement, Defendants shared the supracompetitive profits that their unlawful agreement made possible with Barr/Teva.

140. As a direct and proximate result of Defendants' unlawful conspiracy in restraint of trade, Plaintiffs and/or their assignors have suffered injury to their business and property in an amount to be proven at trial.

Claim IV: Violation of 15 U.S.C. § 2
Conspiracy to Monopolize
(Asserted Against All Defendants)

141. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 114 above as though fully set forth herein.

142. Defendants Boehringer and Barr/Teva combined, conspired and contracted between and among themselves to monopolize trade and commerce in the relevant market and Boehringer did, in fact, monopolize trade in the United States market for 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules.

143. Boehringer and Barr/Teva each committed at least one overt act in furtherance of the conspiracy.

144. At all relevant times, Boehringer possessed market power in the relevant market. Boehringer possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

145. The purpose and effect of Defendants' conspiracy was to allocate 100% of the United States market for 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules to Boehringer through a date as late as July 2015; to allocate 100% of the United States market for generic 200 mg extended-release dypyridamole/25 mg acetylsalicylic acid capsules to Barr/Teva for six months after its eventual launch of generic Aggrenox; and to fix the price which Plaintiffs and/or their assignors paid for 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules at the higher, branded price.

146. Plaintiffs and/or their assignors have purchased substantial amounts of Aggrenox directly from Boehringer. As a result of Defendants' illegal conduct, alleged herein, Plaintiffs have been compelled to pay, and have paid, artificially inflated prices for their 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid capsules requirements. Thus, as a direct and proximate result of Defendants' conspiracy to monopolize, Plaintiffs and/or their assignors have suffered injury to their business and property in an amount to be proven at trial.

X. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

A. A declaration that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act;

B. A permanent injunction enjoining Defendants from continuing their illegal conduct and requiring them to take affirmative steps to dissipate the continuing effects of their prior conduct.

C. An award of Plaintiffs' overcharge damages, in an amount to be determined at trial, trebled;

D. An award of Plaintiffs' costs of suit, including reasonable attorneys' fees as provided by law; and

E. Such other and further relief as the Court deems just and proper.

XI. JURY DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

Dated: March 25, 2015

Respectfully submitted,

/s/ Matthew A. Thomsen

Matthew A. Thomsen
Capozzi Adler P.C.
P.O. Box 5866
Camp Hill, PA 17011
Telephone: (717) 233-4101
Facsimile: (717) 233-4103
Email: matthewt@capozziadler.com
Counsel for Plaintiffs

Of counsel:

Richard Alan Arnold
Scott E. Perwin
Lauren C. Ravkind
Anna T. Neill
Kenny Nachwalter P.A.
1100 Miami Center
201 South Biscayne Boulevard
Miami, FL 33131
Email: sperwin@knpa.com
Email: lravkind@knpa.com
Email: aneill@knpa.com